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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,009	05/16/2001	Alexander Kozak	800.1012	2594

7590 04/15/2003

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EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 04/15/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,009

Applicant(s)

KOZAK ET AL.

Examiner

Sonya Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2, 12, and 30 is/are rejected.
- 7) ☒ Claim(s) 1-26 and 28-33 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-33 are pending in this patent application.

Election/Restrictions

Applicant's election with traverse of a group of claims that is a modification of Group II prepared by the Examiner in Paper No. 8 is acknowledged. The traversal is on the ground(s) that Applicants believe that it would not be unduly burdensome for the Examiner to perform a patentability search for the claims of Groups I-VI together. The claimed compounds all refer to non-steroidal anti-inflammatory drugs covalently conjugated to the sn-2 position of a phospholipid moiety of the general formula I via a bridging group. Applicants respectfully submit that the Examiner's distinction between the hydrocarbon chain being substituted or unsubstituted is overly restrictive since search both possibilities would likewise not involve much extra work.

This is not found persuasive because: although the claimed compounds all refer to non-steroidal anti-inflammatory drugs, the drugs are variously classified. Not to restrict the claims would create an undue burden on the Examiner. Also, a substituted hydrocarbon chain can embrace a plethora of compounds which can be variously classified. If a distinction were not made between substituted and unsubstituted hydrocarbon chains in a restriction, there would be an undue burden on the Examiner.

Upon further consideration, the Examiner has limited R2 and B. (B is in claim 30.) R2 has been limited to the phospholipid head groups which are supported in the specification on page 6, line 15, i.e. choline, ethanolamine, inositol and serine. B has been limited to the blocking groups which are supported in the specification and are

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identified as being useful in protecting NH₂, NH, or SH. See page 19, lines 11-14, i.e. benzyl chloromate, benzyloxycarbonate, diphenylcarbinol, trimethylacetamidocarbinol.

The following generic concept as depicted in claim 1 is identified for examination along with the elected embodiment: R1 is a saturated, unsubstituted hydrocarbon chain having from 2 to 30 carbon atoms, R2 is choline, ethanolamine, inositol or serine, D is indomethacin, Z is a saturated hydrocarbon chain having from 2 to 15 carbon atoms, and X is selected from amino or thio, B is benzyl chloromate, benzyloxycarbonate, diphenylcarbinol, trimethylacetamidocarbinol.

The remaining subject matter of claims 1-26 and 28-33 in part and claim 27 in its entirety stands withdrawn from further consideration under 37 CFR 1.142(b) as constituting other patentably distinct inventions.

The withdrawn subject matter of claims 1-26 and 28-33 in part and claim 27 in its entirety is properly restricted as said subject matter differs in structure and element from the elected subject matter so as to be patentably distinct therefrom, i.e. a reference which anticipated the elected subject matter would not even render obvious the withdrawn subject matter and fields of search are not co-extensive.

Claims 1-26 and 28-33 are objected to as containing non-elected subject matter. This objection may be overcome by limiting the claims to the elected subject matter identified supra.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as containing subject

matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim 30 is directed to "(ii) replacing y with an appropriate blocking group, B", "(iii) preparing an anhydride of the molecule B-X-Z-COOH", "(v) removing the blocking group B from the functional group X", and "(vi) coupling a nonsteroidal anti-inflammatory drug D to the functional group X". The specification does not reasonably provide enablement for the instantly claimed steps.

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification fails to enable the skilled artisan to practice the invention without undue

experimentation. The claims lack positive steps which teach how "(ii) replacing y with an appropriate blocking group, B", "(iii) preparing an anhydride of the molecule B-X-Z-COOH", "(v) removing the blocking group B from the functional group X", and "(vi) coupling a nonsteroidal anti-inflammatory drug D to the functional group X" are performed. There is little predictability in the art of which modifications may be made to the processes as claimed in order to prepare the claimed compound. The terms "replacing", "preparing", "removing", and "coupling" may encompass a great number of processes, however, without some guidance as to how these processes are performed, there would be little predictability in making the invention as claimed. The level of ordinary skill in the art is high. The skilled artisan would have a numerous amount of modifications to perform in the processes as claimed order to obtain the claimed compound, therefore undue experimentation would be required to prepare instant compounds which are useful in the treatment of inflammatory disorders.

This rejection can be overcome by Applicant listing positive process steps in claim 30. See the description of process steps on page 19, lines 3-30 and page 20, lines 1 and 2 and lines 10-16.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 12 recite the limitation "drug derivative". There is improper antecedent basis for this limitation in the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-

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4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

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Sonya Wright

March 31, 2003